ARGUMENTS

By the foregoing amendment, claims 1 and 2 have been amended to further clarify the claimed subject matter and claims 17-35 have been cancelled without prejudice. No new matter has been added. Reconsideration of is respectfully requested.

35 U.S.C. §112 Rejections

In the Office Action, claims 1-35 were rejected under the first paragraph of 35 U.S.C. §112 on grounds that the specification contains inadequate written description to support the recitation of "other anatomical structures of a human or veterinary patient."

In the recent case of *Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co.* 560 F.3d 1366 (Fed. Cir. 2009), an en banc panel of the Federal Circuit Court of Appeal affirmed that 35 U.S.C. §112 includes a written description requirement separate from enablement in determining patentability. In accordance with *Ariad* , Applicant's amended claims are directed to a "method for deterring, inhibiting, preventing or reversing stenosis, restenosis or unwanted proliferation of an artery in a human or veterinary patient..." These amended claims no longer contain reference to "other anatomical structures" as objected to in the Office Action. These amended claims are clearly supported by the written description contained in the specification, including at pages 2-6 and 29-35. Accordingly, the stated rejection under the first paragraph of 35 U.S.C. §112 is believed to have been overcome.

Also, in the Office Action, claims 2 and 21 were rejected under the second paragraph of 35 U.S.C. §112 on grounds that the use of the word "preferably" had rendered those claims indefinite.

By the foregoing amendment, claim 2 has been amended to overcome the stated indefiniteness rejection and claim 21 has been cancelled.

35 U.S.C. §103 Rejections

In the Office Action, claims 1-35 were also rejected under 35 U.S.C. §103 as being obvious over United States Patent No. 5,358,959 (Halpern) in view of United States Patent No. 6,803,375 (Chandy et al.) and further in view of United States Patent No. 6,613,083 (Ault).

The first paragraph of page 1 of the present application states as follows:

> This application is a continuation-in-part of U.S. Patent Application Serial No. 09/479,391, filed January 6, 2000. In addition, this application claims priority to United States Provisional Application Serial No. 60/422,712 filed October 30, 2002. The disclosures of both the above-identified patent application and the above-identified provisional patent are expressly incorporated herein by reference.

Chandy et al. issued from parent application Serial No. 09/479,391. Thus, this application is a continuation in part of Chandy et al. Chandy et al. issued in 2004, subsequent to the filing date of the present application, without any prior pre-grant publication. However, it is noted that the PCT international counterpart of Chandy was published as PCT International Patent Publication WO2001/49663 on July 12, 2001.

In support of the stated obviousness rejection, the Office Action sattes at pages 8-9 that Halpern et al. teaches the use of imidazole compounds, including clotrimazole, for the treatment of atherosclerosis, inhibiting unwanted endothelial and smooth muscle proliferation and for delaying or avoiding restenosis. The Examiner concedes, on page 9 of the Office Action, that Halpern et al. fails to teach the presently-claimed compounds. However, the Examiner contends that Chandy et al. teaches that "preferred compounds possess the same activities to inhibit endothelial cells" and that "one skilled in the art would have assumed that the substitution of another compound that possesses the same activity would achieve the same results in the absence of evidence to the contrary." Applicant respectfully disagrees with this reasoning.

Halpern et al. would not lead any person of skill in the art to assume that, simply because certain imidazole compounds that inhibit Ca++ activated potassium channels were also found to have activity against restenosis or atherosclerosis, other classes of compounds that inhibit Ca++ activated potassium channels would *also* have the same activity against restenosis or atherosclerosis. To the contrary, Halpern et al. actually teaches away from such assumption. Specifically, at column 3, lines 55 through 63, Halpern et al. states as follows:

> Other specific inhibitors of the Ca++ activated potassium channel (such as charybdotoxin, caliotoxin and iberotoxin) do not inhibit proliferation of endothelial or vascular smooth muscle cells. Moreover, inhibitors of other transport systems that are activated by mitogens, such as ouabain (highly specific inhibitor of the Na/K pump) and amiloride (inhibitor of Na/H exchange) do not inhibit cell proliferation. Thus, the results obtained by the inventor are surprising.

The law requires that Halpern et al. be considered in its entirety, i.e., as a whole, including the above-quoted portion that clearly teaches away from any expectation or probability that Applicant's claimed compounds would be effective for the treatment of stenosis, restenosis or unwanted proliferation of an artery. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984).

In view of the express teaching by Halpern et al. that not all inhibitors of Ca++ activated potassium channels inhibit proliferation of endothelial or vascular smooth muscle cells, there would have been no basis to predict with reasonable certainty that the compounds disclosed by Chandy et al. would be effective for the presently claimed methods. Such predictability of the outcome is a necessary component of any finding of obviousness. In this regard, United States Supreme Court has stated in *KSR International Co.* v. *Teleflex Inc.*, 550 U.S. at 1, 82 USPQ2d at 1391 (2007) that:

> When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or

a different one. If a person of ordinary skill can implement a predictable variation, §103 likely bars its patentability.

Thus, Applicant's presently claimed method for treatment of stenosis, restenosis or unwanted proliferation of an artery id not obvious over Halpern et al. in view of Chandy et al.

Alt is relied upon only for teaching the concept of coating of stents for implantation. Alt describes a coated stent that delivers an effective dose of the immunosuppressant drug tacrolimus to the vessel wall. The tacrolimus is purportedly delivered at a rate and in a concentration that both encourages proliferation of smooth muscle cells and limits conversion of such cells to the secretory type muscle cells. Alt ads nothing to cure the deficiencies of the Halpern et al./Chandy et al. combination as basis for the stated obviousness rejection.

Conclusion

For the foregoing reasons, Applicant believes that claims 1-16 are in condition for allowance and should be passed to issue. No fee is seen to be due in connection with the filing of this response. However, in the event that a fee is properly deemed to be due, the Commissioner is hereby authorized to charge such fee to Deposit Account No. 50-0878.

Date: May 24, 2010

Respectfully submitted,
STOUT, UXA, BUYAN & MULLINS, LLP

/Robert D. Buyan/
Robert D. Buyan, Reg. No. 32,460

4 Venture, Suite 300
Irvine, CA 92618
Telephone: (949) 450-1750
Facsimile: (949) 450-1764
e mail: rbuyan@patlawyers.com